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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/393,173	09/09/99	CURIEL	D 6163

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HM12/0329

EXAMINER

BECKERLEG, A

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

03/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/393,173

Applicant(s)

CURIEL ET AL.

Examiner

Anne M Beckerleg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Continued Prosecution Application

The request filed on 1/8/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/393,173 is acceptable and a CPA has been established. Claims 1-3, and 5-10 are active and pending in the instant application. An action on the CPA follows. It is noted that the examiner and the art unit for this application has changed.

Those sections of Title 35, US code, not included in this action, can be found in the previous office action, paper no. 5.

Claim Rejections - 35 USC § 112

Claims 2-3 and 5-10 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making an inducible adenoviral vector encoding the bax gene and using said vector to express bax in tumor cells *in vitro*, does not reasonably provide enablement for the treatment of any neoplastic disease, including ovarian cancer, by administering to a mammal by any route of administration any inducible adenoviral vector encoding bax. The specification does not enable any person skilled in the art or to which it most nearly pertains, or

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with which it is most nearly connected, to use the invention commensurate in scope with these claims for reasons ^{of} record as discussed in detail in papers no. 2 and 5.

It is noted that applicants have not provided any arguments in response to this rejection as presented in the office action mailed on 7/6/00, paper no. 5. Therefore, the rejection of record is maintained. See the previous office actions mailed on 12/13/99 (paper no. 2) and 7/6/00 (paper no. 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 1 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/25507, published on 8/22/96, hereafter referred to as Seth et al. in view of Massie et al. (1998) J. Virol., Vol. 72 (3) 2289-2296. The applicant claims an inducible recombinant adenoviral vector encoding a pro-apoptotic *bax* gene. Seth et al. teaches the construction of an adenoviral vector which can be modified to encode a gene useful for eradicating tumor cells via the toxic effects of the expressed gene. Seth et al. teaches that genes useful for inclusion in the adenoviral vector include BAX (Seth et al., page 21, lines 27-35). Seth et al. does not specifically teach an inducible adenoviral vector. Massie et al. supplements Seth et al. by teaching a tetracycline inducible adenoviral vector suitable for expressing toxic genes in cells (Massie et al., page 2289, abstract, and page 2290, Figure 1). Massie et al. provides motivation for using an inducible system to express toxic gene in order to more tightly regulate their expression. Massie et al. further provides motivation for using an inducible adenovirus for the expression of pro-apoptotic genes by teaching the successful use of the inducible adenoviral vector to express the pro-apoptotic $\Delta R1$ and ORF5 proteins (Massie et al., page 2295, column 1, paragraph 4). Thus, based on the motivation to use an inducible adenoviral vector to express a pro-apoptotic gene as taught by Massie et al., it would have been *prima facie* obvious to the skilled artisan to substitute the inducible adenoviral vector taught by Massie et al. for the adenoviral vector taught by Seth et al. in order to express BAX in cells. Further, the skilled artisan would have had a reasonable expectation of success in making an using an inducible adenoviral vector to express BAX in cells

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based on the high level of skill in molecular biology at the time of filing and the successful use of the inducible adenoviral vector taught by Massie et al. to express other apoptotic genes.

It is noted that previous arguments filed on 4/18/00, paper no. 4, in regards to the Seth et al. reference have been fully considered in view of the new grounds of rejection and have not been found persuasive in overcoming the instant grounds of rejection. The applicant argued that Seth et al. does not teach the cre-loxP inducible system disclosed by the applicants. However, the applicant is reminded that claim 1 is not limited to an inducible cre-loxP adenoviral vector but reads broadly on any type of inducible adenoviral vector encoding BAX.

No claim are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Karen Hauda, can be reached at (703) 305-6608. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The official fax number is (703) 308-4242.

Dr. A.M.S. Beckerleg

A handwritten signature in black ink, appearing to read 'AM Beckerleg', with a long horizontal flourish extending to the right.